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(54) **Peroxydiphosphate toothpaste composition**

(57) A toothpaste composition containing a peroxydiphosphate salt (especially the tetrapotassium salt) and optionally a fluorine-providing anticaries agent as substantially the sole oral chemically active agents, in combination with specially selected polishing material, thickeners, and humectants.

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SPECIFICATION

Peroxydiphosphate toothpaste composition

The present invention relates to stabilized toothpaste compositions and especially to such compositions containing a peroxydiphosphate salt (PDP) preferably the tetrapotassium salt (KPDP), and optionally a fluorine-providing anticaries agent as substantially the sole oral chemically active agents.

It is known in the art that hydrogen peroxide and other peroxygen-containing agents are effective against caries, dentral plaque, gingivitis, periodontitis, mouth odour, and tooth stains. In fact, the essential active PDP employed herein has been previously disclosed as an effective antiodour agent in an oral composition. Thus, U.S. 4,041,149 issued 9th August, 1977 to Maria Gaffar, Abdul Gaffar (applicant herein) and John Hauschild discloses the effectiveness of such oral compositions, the PDP being activated by the salivary phosphatases to generate hydrogen peroxide and/or active or nascent oxygen which deodorizes the oral cavity.

Other oral compositions have been prepared in which a PDP salt is employed as an additive to inhibit the stains normally produced by the essential oral chemically active agent in the compositions. More particularly, U.S. 4,273,759 issued 16th June, 1981 to Abdul Gaffar and Maria C. Gaffar discloses oral compositions containing PDP salts to inhibit stains normally produced by cationic nitrogen-containing antibacterial antiplaque agents and U.S. application Serial No. 117,410 filed 31st January, 1980 by Abdul Gaffar discloses oral compositions containing PDP salts to inhibit stains normally produced by a tranexamic acid antigingivitis agent.

It is also known however that most peroxy compounds such as hydrogen peroxide and metal peroxides such as magnesium peroxide are unstable in storage, continuously losing the ability to release active or nascent oxygen over relatively short periods of time, especially in the presence of various other incompatible inorganic and organic materials such as many of the usual excipients in oral compositions, especially toothpaste (including dental cream) compositions. Thus, in French Patent 2325304 (75 29482) published 22nd April, 1977, this problem is recognized and solved by a relatively difficult and costly means involving preventing the peroxidized component such as magnesium peroxide from contacting an acidic material reactive therewith, as by coating the said component and acidic material with suitable excipients, prior to and until the moment of use in the oral cavity.

PDP salts are regarded as substantially more stable than hydrogen peroxide and magnesium peroxide. In the said U.S.P. 4,041,149 it is disclosed that a 10% aqueous solution of the preferred KPDP shows no active oxygen loss after 4 months at 25°C and a loss of 3% after 6 months at 50°C. It was accordingly concluded, and so indicated in the patent, that "this stability permits long shelf-life of oral compositions containing the said peroxydiphosphate compound".

The aforesaid conclusion has however been found to be for the most part unjustified. Extensive experiments with oral compositions containing KPDP in combination with a variety of common excipients such as polishing material (dental abrasives), humectants, thickeners, flavours and the like have established hitherto unknown incompatibilities resulting in unduly short storage stability or shelf-life, premature loss of active oxygen, impairment of the desired functions of the several components of the compositions and/or unacceptable chemical and/or physical and/or cosmetic properties of the compositions and the like.

The present invention aims to provide oral compositions which will not be subject to one or more of the above disadvantages and deficiencies. This invention also aims to provide stable oral compositions containing a PDP salt, and optionally a fluorine-providing anticaries compound, as substantially the only oral chemically active agents.

According to the present invention a toothpaste composition comprises:

I, an oral vehicle,

II, as substantially the only oral chemically active agents,

A. 0 to about 2% by weight of a fluorine-providing anticaries compound and

B. about 1 to about 7% by weight of a peroxydiphosphate salt

III, about 10 to about 75% by weight of at least one polishing material comprising silica or hydrated alumina or mixtures thereof,

IV, about 0.5 to about 10% by weight of at least one thickener comprising colloidal silica, synthetic hectorite, poly(methyl vinyl ether/maleic anhydride), carboxyvinyl polymer, carboxymethyl cellulose, hydroxypropyl methyl cellulose, hydroxybutyl methyl cellulose, or hydroxyethyl cellulose or mixtures thereof, and

V, about 5 to about 75% by weight of polyethylene glycol as humectant.

The above defined oral chemically active components IIA and IIB are typically and preferably inorganic. These compositions which comprise mutually compatible components enable the attainment of one or more unexpected improvements such as unexpectedly improved storage stability or shelf-life, acceptable chemical and/or physical and/or cosmetic properties, retention of the desired functions of the individual components, and the like. As employed herein, the term "oral chemically active agent" refers to anticaries, antiplaque, antigingivitis, antiperiodontitis, antiodour or bleaching agents or the like which act chemically on, with respect to or in relation to the teeth, oral tissues and/or oral environment, in contrast to polishing material (dental abrasives) which act physically on the teeth and inert

components which determine the properties of the oral composition per se such as thickeners, humectants, flavours, surfactants, sweeteners, colours, whiteners, brighteners, preservatives, and other conventional excipients. The essential PDP salts employed herein, especially KPDP, fall in the category of each of the aforementioned oral chemically active agents. The oral compositions of this invention, for similar reasons, are mutually exclusive of the antibacterial antiplaque compositions of the above mentioned U.S. 4,273,759 and the antigingivitis compositions of the above mentioned U.S. application serial No. 117,410.

Any of the alkali metal, alkaline earth metal, metal or ammonium peroxydiphosphates or their corresponding acid salts that are water-soluble to the extent of about 0.001 weight percent can be used in the compositions of this invention. Examples of these are tetrapotassium peroxidiphosphate ($K_4P_2O_8$), tetralithium peroxydiphosphate ($Li_4P_2O_8$), tetrasodium peroxydiphosphate ($Na_4P_2O_8$), tripotassium monosodium peroxydiphosphate ($K_3NaP_2O_8$), dipotassium disodium peroxydiphosphate ($K_2Na_2P_2O_8 2H_2O$), monopotassium trisodium peroxydiphosphate ($KNa_3P_2O_8$), monopotassium monosodium dihydrogen peroxydiphosphate ($KNaH_2P_2O_8$), trilithium monopotassium peroxydiphosphate ($Li_3KP_2O_8$), dilithium dipotassium peroxydiphosphate ($Li_2K_2P_2O_8$), monolithium tripotassium peroxydiphosphate ($LiK_3P_2O_8$), trilithium monosodium peroxydiphosphate ($Li_3NaP_2O_8$), dilithium disodium peroxydiphosphate ($Li_2Na_2P_2O_8$), monolithium trisodium peroxydiphosphate ($LiNa_3P_2O_8$), monolithium monosodium dihydrogen peroxydiphosphate ($LiNaH_2P_2O_8$), and monolithium monopotassium dihydrogen peroxydiphosphate ($LiKH_2P_2O_8$), in addition to dizinc peroxydiphosphate ($Zn_2P_2O_8$), tetraammonium peroxydiphosphate dihydrate ($(NH_4)_4P_2O_8 2H_2O$), and the acid salts of group II metals such as barium dihydrogen peroxydiphosphate ($BaH_2P_2O_8$), calcium dihydrogen peroxydiphosphate ($CaH_2P_2O_8$, and the like.

The preferred tetrapotassium peroxydiphosphate (KPDP) is a stable, odourless, finely divided, free-flowing, white, non-hygroscopic crystalline solid having a molecular weight of 346.35 and an active oxygen content of 4.5%. The potassium peroxydiphosphate is 47—51% water-soluble at 0°C—61°C, but insoluble in common solvents such as acetonitrile, alcohols, ethers, ketones, dimethylformamide, dimethyl sulphoxide, and the like. A 2% aqueous solution has a pH of about 9.6 and a saturated solution thereof a pH of about 10.9.

The essential PDP salt (or mixture thereof) is employed in an amount effective for achieving the desired therapeutic, antiodour, bleaching or other function, typically constituting about 1 to about 7% by weight, preferably about 2 to about 5% by weight, more preferably about 3% by weight, of the oral compositions of the present invention.

The fluorine-providing anticaries compounds optionally present in these oral preparations may be slightly soluble in water or may be fully water-soluble. They are characterised by their ability to release fluoride ions in water and by substantial freedom from reaction with other compounds of the oral preparation. Among these materials are inorganic fluoride salts, such as soluble alkali metal, alkaline earth metal and heavy metal salts, for example, sodium fluoride, potassium fluoride, ammonium fluoride, calcium fluoride, a copper fluoride such as cuprous fluoride, zinc fluoride, a tin fluoride such as stannic fluoride or stannous chlorofluoride, barium fluoride, sodium fluorosilicate, ammonium fluorosilicate, sodium fluorozirconate, sodium monofluorophosphate, aluminium mono- and di-fluorophosphate, and fluorinated sodium calcium pyrophosphate. Alkali metal and tin fluorides, such as sodium and stannous fluorides, sodium monofluorophosphate (MFP) and mixtures thereof, are preferred.

The amount of the fluorine-providing compound is dependent to some extent upon the type of compound, its solubility, and the type of oral preparation, but it must be a nontoxic amount. An amount of such compound which releases a maximum of about 1% of fluoride ion by weight of the preparation is considered satisfactory. Any suitable minimum amount of such compound may be used, but it is preferable to employ sufficient compound to release about 0.005 to 1%, and preferably about 0.1% of fluoride ion. Typically, especially in the cases of MFP, alkali metal fluorides and stannous fluoride, this component is present in an amount of about 0.01 to about 2% by weight, based on the weight of the preparation, and preferably in the range of about 0.05 to about 1% by weight, especially about 0.76% by weight.

To achieve the desired results herein, the polishing material, component III, is a silica or a hydrated alumina (alpha alumina trihydrate) or mixtures thereof, hydrated alumina being preferred. Both of these are per se conventional dentral abrasive polishing materials with average particle sizes ranging from about 0.1 to about 30 microns, preferably about 1.0 to about 15 microns. The following are illustrative of some preferred polishing materials.

The silica polishing material may be in the form of crystalline silica having particle sizes up to 5 microns, a mean particle size of up to about 1.1 microns and a surface area of up to 50,000 cm^2/gm, silica gels, Zeodent (e.g. Zeodent 49 or 119) precipitated silica products of J. M. Huber Corporation, complex amorphous alkali metal aluminosilicates, and the like. The types of silica dental abrasives disclosed in U.S. 3,862,307 issued 21st January, 1975 may be employed.

When visually clear gels are employed, a polishing agent of silica xerogel or colloidal silica such as those sold under the trademark SYLOID (W. R. Grace and Co. e.g. Syloid 63, 64, 72 or 74) or under the trademark SANTOCEL as Santocel 100 and alkali metal aluminosilicate complexes are particularly

useful, since they have refractive indices close to the refractive indices of gelling agent-liquid (including water and/or humectant) systems commonly used in dentifrices.

Hydrated alumina, particularly the hydrated alumina sold by Alcoa as C333, which has an alumina content of 64.9% by weight, a silica content of 0.008%, a ferric oxide content of 0.003%, and a moisture content of 0.37%, at 100°C, and which has a specific gravity of 2.42 and a particle size such that 100% of the particles are less than 50 microns and 84% of the particles are less than 20 microns, is particularly desirable. Hydrated alumina has been found to be the most compatible polishing material herein.

The polishing material is generally present in amounts ranging from 10 to about 75% by weight, preferably about 35 to 65% by weight, more preferably about 45 to about 55% by weight in these toothpaste compositions.

The thickener component IV, employed in proportions of about 0.5 to about 10 preferably about 1 to about 5% by weight of the composition should be one or a mixture of the above-named members of the group. A preferred thickener is synthetic hectorite, a synthetic colloidal magnesium alkali metal silicate complex clay available for example as Laponite (e.g. XLG, XLS, or D) marketed by Laporte Industries Limited. Laponite D analysis shows, approximately by weight, 58.00% SiO_2, 25.40% MgO, 3.05% Na_2O, 0.98% Li_2O, and some water and trace metals. Its true specific gravity is 2.53 and it has an apparent bulk density (g/ml at 8% moisture) of 1.0.

Other thickeners include carboxymethyl cellulose, hydroxybutyl methyl cellulose, hydroxypropyl methyl cellulose, and preferably hydroxyethyl cellulose (e.g. available as Natrosol).

A poly(methyl vinyl ether/maleic anhydride) thickener is available for example as Gantrez AN 139 (GAF Corporation) and a colloidal silica thickener as a more finely ground Syloid (e.g. 244).

A carboxyvinyl polymer useful as a thickener is for example available as Carbopol (e.g. 934, 940, 941). These products of B. F. Goodrich Co. are described in U.S. 2,798,053, 2,923,692 and 2,980,655, being essentially colloidally water-soluble acidic carboxylic polymers of acrylic acid crossed-linked with about 0.75 to about 2.0% of a cross-linking agent of polyallyl sucrose or polyallyl pentaerythritol.

The humectant, component V, employed in proportions of about 5 to 75, preferable about 10 to 45, more preferably about 15 to 35% by weight of the toothpaste compositions of this invention is polyethylene glycol (e.g. 400 or 600). This component of relatively low molecular weight (e.g. about 300 to about 1,000) often also functions as the liquid carrier vehicle, alone or in combination with water and/or ethanol.

Any flavour optionally but preferably employed in the PDP-containing toothpaste compositions of this invention should of course also be compatible with the PDP.

Flavour is typically included in the oral compositions of this invention in approximate weight proportions of 0.01 to 3.0%, preferably 0.5 to 2.0%, more preferably 0.75 to 1.0%. Some illustrative examples of compatible flavours include pulegol, anethole, isoeugenol, guaiacol, creosol, thymol, menthol, cineol, eugenol, clove bud oil, peppermint and spearmint extracts, carvone, methyl paracresol, eucalyptol, safrole, anisol and the like.

The solid and liquid components of the compositions of this invention are proportioned in conventional manner to form a pasty, creamy or gelled mass which may be dispensed or extruded from a pressurized container or from a flexible or collapsible container or tube, e.g. of aluminium, lined lead or plastic or the like. The compositions may be substantially anhydrous but generally contain about 1 to about 25, typically about 5 to about 20% by weight of water. These compositions preferably have a pH measured as a 20% aqueous slurry of 7.8 to about 10.5 more preferably about 8.5 to about 10.5, especially about 9.5 to 10.5 since the PDP, especially KPDP, appears to be more stable, i.e. with better retention of active oxygen activity, at these more alkaline ranges in the presence of the other components of the compositions. The pH can be controlled by inclusion of the required amounts of acidic substances such as citric or benzoic acid, basic substances such as sodium hydroxide, and/or buffering agents such as sodium citrate, benzoate, bicarbonate or carbonate, disodium hydrogen phosphate, sodium dihydrogen phosphate, or mixtures thereof. It should be noted that selection of the proper dental abrasive or polishing material is important for maintenance of the above described alkaline pH ranges, since most conventional polishing materials cannot be employed in the compositions of the present invention at such pH ranges. For example, when insoluble sodium metaphosphate (IMP) abrasive is employed with the other above-defined components of these compositions and the pH adjusted to 9.7, the composition loses substantial amounts of its available oxygen when aged at 120°F (49°C) and the pH shifts down to about 7.2. In contrast, although compositions of the present invention with silica as polishing material show poor stability at an "as is" pH of 7.7 the composition is stabilized when the pH is adjusted upwards as indicated above, e.g. to 9.7, and the pH does not shift significantly with aging. Hydrated alumina performs in excellent manner in this respect since its normal pH falls within the above ranges.

The toothpaste compositions of the present invention may contain a non-soap synthetic sufficiently water soluble organic anionic or nonionic surfactant in concentrations generally ranging from about 0.05 to about 10, preferably about 0.5 to about 5% by weight, to promote wetting, detersive and foaming properties.

U.S. Patent No. 4,041,149 discloses such suitable anionic surfactants in column 4, lines 31—38

and such suitable nonionic surfactants in column 8 lines 30—68 and column 9, lines 1—12, which passages are incorporated herein by reference thereto.

Thus, suitable anionic surfactants include, for example, the water-soluble salts of higher fatty acid monoglyceride monosulphate detergents (e.g. sodium coconut fatty acid monoglyceride monosulphate), higher alkyl sulphates (e.g. sodium lauryl sulphate), alkyl aryl sulphonates (e.g. sodium dodecyl benzene sulphonate), higher fatty acid esters of 1,2-dihydroxypropanesulphonate and the like.

Suitable nonionic organic surface active compounds include water-soluble products which are derived from the condensation of an alkylene oxide or equivalent reactant and a reactive-hydrogen hydrophobe. The hydrophobic organic compounds may be aliphatic, aromatic or heterocyclic, although the first two classes are preferred. The preferred types of hydrophobes are higher aliphatic alcohols and alkyl phenols, although others may be used such as carboxylic acids, carboxamides, sulphoamides, etc. The ethylene oxide condensates with higher-alkyl phenols represent a preferred class of nonionic compounds. Usually the hydrophobic moiety should contain at least about 8 carbon atoms, and may contain as many as about 50 carbon atoms or more. The amount of alkylene oxide will vary considerably, depending upon the hydrophobe, but as a general guide and rule, at least about 5 moles of alkylene oxide per mole of hydrophobe should be used. The upper limit of alkylene oxide will vary also, but no particular criticality can be ascribed thereto. As much as 200 or more moles of alkylene oxide per mole of hydrophobe may be employed. While ethylene oxide is the preferred and predominating oxyalkylating reagent, other lower alkylene oxides such as propylene oxide, butylene oxide, and the like, may also be used or substituted in part for the ethylene oxide. Other nonionic compounds which are suitable are the polyoxyalkylene esters of the organic acids such as the higher fatty acids, the rosin acids, tall oil acids, acids from petroleum oxidation products, etc. These esters will usually contain from about 10 to about 22 carbon atoms in the acid moiety and from about 12 to about 30 moles of ethylene oxide or its equivalent.

Still other nonionic surfactants are the alkylene oxide condensates with the higher fatty acid amides. The fatty acid group will generally contain from about 8 to about 22 carbon atoms and this will be condensed with about 10 to about 50 moles of ethylene oxide as the preferred illustration. The corresponding carboxyamides and sulphonamides may also be used as substantial equivalents.

Still another class of nonionic products are the oxyalkylated higher aliphatic alcohols. The fatty alcohols should contain at least 6 carbon atoms, and preferably at least about 8 carbon atoms. The most preferred alcohols are lauryl, myristyl, cetyl, stearyl and oleyl alcohols and the said alcohols should be condensed with at least about 6 moles of ethylene oxide, and preferably about 10 to 30 moles of ethylene oxide. A typical nonionic product is oleyl alcohol condensed with 15 moles of ethylene oxide.

Pluronic (Registered Trade Mark) type nonionic surfactants (polyoxyethylene polyoxypropylene block polymers) such as Pluronic F108 and F127 may also be employed.

Various other conventional toothpaste adjuvants or excipients may be included such as whitening or colouring agents, preservatives, silicones, ammoniated materials such as urea or diammonium phosphate, and sweetening agents in amounts ranging from about 0.01 to about 5% by weight or more. Suitable sweetening agents include for example sorbitol, xylitol, sodium cyclamate, perillartine, D-tryptophan, dihydrochalcones, and the like, and preferably saccharin.

In the practice of the present invention, the toothpaste is applied regularly to the oral cavity, especially to the dental enamel, preferably from about 1 to 3 times dialy, for durations of preferably at least about 10 seconds, more preferably at least about 60 seconds, in the usual required amounts employed in brushing the teeth.

The invention may be put into practice in various ways and a number of specific embodiments will be described to illustrate the invention with reference to the accompanying examples. All amounts and proportions referred to herein and in the appended claims are by weight unless otherwise indicated.

In the following examples the stability of the KPDP can be evaluated by monitoring active oxygen (A.O.) contents by the following procedure:

KPDP readily hydrolyzes in an acid medium as follows:

$$P_2O_8^{-4} + 2H_2O \text{—} 2HPO_4^{-2} + H_2O_2$$

An excess of ferrous ammonium sulphate is added to reduce peroxide:

$$2Fe(NH_4)_2(SO_4)_2 + H_2O_2 + H_2SO_4 \text{—} Fe_2(SO_4)_3 + 2(NH_4)_2SO_4 + 2H_2O$$

The excess of ferrous ion is back titrated with ceric sulphate:

$$2Fe(NH_4)_2(SO_4)_2 + 2Ce(SO_4)_2 \text{—} CE_2(SO_4)_3 + Fe_2(SO_4)_3 + 2(NH_4)_2SO_4$$

The A.O. is found by difference.

EXAMPLES 1 to 3

A number of toothpaste compositions were made up and details of their ingredients and proportions are given in Table I.

TABLE I

Example	(% by weight) 1	2	3
Water, distilled	19.69	17.0	18.0
Laponite XLG	2.4	2.4	2.5
PEG 600	8.7	8.0	7.0
Pluronic F108[1]	4.3	4.0	4.5
Sodium benzoate	0.54	0.5	0.54
Sodium saccharin	0.22	0.2	0.22
Flavour	0.55	0.5	0.55
Water, distilled	7.6	7.0	7.6
KPDP	3.0	3.0	3.0
Hydrated alumina	53.0	50.0	53.0

Example	Active Oxygen (% by weight) 1	2	3
Theoretical	0.126	0.126	0.126
Initial at RT	0.123	0.130	0.122
Aged 7 weeks at 100°F(38°C)	0.123	0.131	0.130

[1] The above examples show the sequence of addition of underlined individual or grouped components.

EXAMPLES 4 and 5

Further toothpastes were made up, details being given in Table II.

TABLE II

	(% by weight)	
Example	4	5
Laponite XLG	2.0	
Laponite XLS		5.8
Natrosol 250 MR[1]	0.5	
KPDP	3.0	3.0
Sodium benzoate	0.5	
Sodium saccharin	0.2	0.2
PEG 600	10.0	15.0
Hydrated alumina	49.0	37.0
SLS (sodium lauryl sulphate)	1.5	1.5
Flavour	0.5	0.5
Water	32.8	37.0
(pH)	(10.0)	(9.6)

	Active Oxygen (% by weight)	
Example	4	5
Initial at RT	0.124	0.127
Aged 3 weeks at 120°F (49°C)	0.130	0.127
Aged 6 weeks at 120°F (49°C)	0.120	0.112
Aged 9 weeks at 120°F (49°C)	0.116	0.119

[1] Hydroxyethyl cellulose

EXAMPLES 6 and 7

Further toothpastes were made up, details being given in Table III.

TABLE III

Example	(% by weight) 6	7
Syloid 244	7.15	7.3
Zeo 49 (Huber silica)	19.36	19.8
PEG 600	50.6	51.7
KPDP	3.0	3.4
Sodium saccharin	0.2	0.22
Sodium benzoate	0.5	0.56
TiO_2	0.55	0.56
Water	17.14	14.8
SLS	1.0	1.66
_____[1]		
Flavour	0.5	—
(pH adjusted with 50% NaOH)	(9.7)	(9.2)

Example	Active Oxygen (% by weight) 6	7
Initial at RT	0.125	0.148
Aged 3 weeks at 120°F (49°C)	0.118	0.126
Aged 6 weeks at 120°F (49°C)	0.110	0.128
Aged 9 weeks at 120°F (49°C)	0.108	0.132

[1] See Note 1 on Table I

EXAMPLES 8, 9 and 10

Further toothpastes were made up, details being given in Table IV.

TABLE IV

	(% by weight)		
Example	8	9	10
Hydroxyethyl cellulose	1.0	1.0	1.0
PEG 600	20.0	20.0	20.0
Sodium benzoate	0.5	0.5	0.5
Sodium saccharin	0.2	0.2	0.2
Hydrated alumina	47.0	47.0	48.0
KPDP	3.0	3.0	3.0
H_2O	26.05	26.05	25.6
Flavour	0.75	0.75	0.5
SLS	1.5	1.5	—
Nonionic Surfactant [1]	—	—	1.2
(pH)	(10)	(10)	
	Active Oxygen (% by weight)		
Example	8	9	10
Initial at RT	0.136	0.131	0.130
Aged 6 weeks at 120°F (49°C)	0.134	0.133	
Aged 9 weeks at 120°F (49°C)			0.130

[1] Polyethoxylated (20 E.O.) sorbitan monoisostearate.

The formulations in the above examples exhibit good to excellent active oxygen stability in storage. In contrast, the only toothpaste formulation disclosed in U.S. 4,041,149, namely Example 1, containing incompatible components (glycerine, precipitated calcium carbonate and dicalcium phosphate dihydrate) exhibits unacceptable active oxygen stability.

EXAMPLES 11A and 11B

A toothpaste in accordance with the invention (Example 11A) and a control (Example 11B) were made up, details being given in Table V below.

TABLE V

Example	(% by weight) 11A	11B
Natrosol 250 MR	1.0	1.0
PEG 600	20.0	20.0
Hydrated alumina	52.0	52.0
SLS	1.5	1.5
Sodium benzoate	0.5	0.5
Sodium saccharin	0.2	0.2
KPDP	3.0	—
Deionized water	25.8	25.8
(pH at 10.2)		

The above chemically, physically and cosmetically stable formulation according to the present invention (Example 11A) and a control formulation omitting the KPDP (Example 11B) were evaluated for effectiveness in reducing gingivitis and plaque in a scientifically conducted 12 week test on groups of 10 beagle dogs (5 male and 5 female). The results (average of 10 dogs) are shown in Table VI below.

TABLE VI

Example	11B	11A
Gingiva Index		
Initial	0.85	0.88
Final	0.79	0.47
Plaque Unit Index	1.22	0.96

These results established that the addition of the KPDP to the control formulation significantly reduced both the gingival index and the plaque index. In contrast, a simultaneous test using a nonaqueous formulation containing propylene glycol humectant, hydroxypropyl cellulose thickener and Dical abrasive increased the plaque index and a similar test using an aqueous neutral formulation containing PEG 600 humectant, hydroxyethyl cellulose thickener and IMP abrasive increased both the gingival and plaque indices.

It has been shown above that formulations according to the invention containing polyethylene glycol (PEG) humectant are highly stable against loss of available oxygen. The criticality of combinations of required components in such formulations, and the mutuality of stabilization therein, is established for example by the fact that PEG acts upon and drastically reduces the effectiveness of KPDP as a source of available oxygen in the absence of the other defined components. Thus, aqueous KPDP solutions buffered to pH 7 are stable at 120°F (49°C) for 9 weeks, but the addition of varying amounts (3%, 15%, 40%) of PEG to 3% KPDP solutions (conducted in triplicate) yield, when aged 9 weeks at 100°F (38°C) and 120°F (49°C), the average results given in Table VII below:

TABLE VII

PEG	Initial	% of Available Oxygen 1 wk 120°F	3 wks 120°F	6 wks 120°F	9 wks 120°F	6 wks 100°F	9 wks 100°F
3%	0.126	0.107	.050	0.041	0	0.086	0.061
15%	0.115	0.113	0.066	0.053	0.023	0.088	0.066
40%	0.120	0.116	0.091	0.084	0.029	0.091	0.072
		Average % Loss					
		6.7	42.4	50.4	85.2	26.5	44.9

CLAIMS

1. A toothpaste composition comprising:

I, an oral vehicle

II, as substantially the only oral chemically active agents,

A. 0 to about 2% by weight of a fluorine-providing anticaries compound and

B. about 1 to about 7% by weight of a peroxydiphosphate salt,

III, about 10 to about 75% by weight of at least one polishing material comprising silica or hydrated alumina or mixtures thereof,

IV, about 0.5 to about 10% by weight of at least one thickener comprising colloidal silica, synthetic hectorite, poly(methyl vinyl ether/maleic anhydride), carboxyvinyl polymer, carboxymethyl cellulose, hydroxypropyl methyl cellulose, hydroxybutyl methyl cellulose, or hydroxyethyl cellulose or mixtures thereof, and,

V, about 5 to about 75% by weight of polyethylene glycol as humectant.

2. A composition as claimed in Claim 1 in which the polishing material comprises hydrated alumina.

3. A composition as claimed in Claim 1 or Claim 2 in which the polishing material comprises silica.

4. A composition as claimed in Claim 1, 2 or in which the thickener comprises synthetic hectorite.

5. A composition as claimed in Claim 1, 2, 3 or 4, in which the thickener comprises hydroxyethyl cellulose.

6. A composition as claimed in any one of Claims 1 to 5 in which the said peroxydiphosphate salt is tetrapotassium peroxydiphosphate.

7. A composition as claimed in any one of Claims 1 to 6 having a pH of 7.8 to about 10.5.

8. A composition as claimed in Claim 1 substantially as specifically described herein with reference to any one of Examples 1 to 10 or 11A.

9. A composition as claimed in any one of Claims 1 to 8 for use in treating the oral cavity to reduce incidence of caries.

10. A method comprising applying to the oral cavity a composition as claimed in any one of Claims 1 to 8.

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